Application No. 10/540,086

Paper Dated: October 22, 2009

In Reply to USPTO Correspondence of June 22, 2009

Attorney Docket No. 4544-051936

AMENDMENTS TO THE SPECIFICATION

Please delete the paragraph beginning on page 2, line 11 to page 3, line 7 of the specification as originally filed and replace it with the following amended paragraph:

-- Here we report a PCR assay that enables the precise identification of closely related mycobacteria belonging to the MTB complex. hupß gene encoding histone-like protein of M. tuberculosis has been exploited as a target for detection and differentiation of M. tuberculosis and M. bovis. The hupß gene target not only permits differentiation of M. tuberculosis from M. bovis, but also from among other members of the MTB complex, non-tuberculous mycobacteria as well as non-mycobacterial species tested. The assay would prove useful especially in developing countries with a high incidence of infected livestock (Grange, 2001). M. bovis has been known to spread to humans from infected cattle by the aerosol route or by consumption of infected/contaminated dairy products (Zoonotic tuberculosis) (Moda et al., 1996; Cosivi et al., Although bovine tuberculosis had been largely eradicated in developed countries, recently resurgence of bovine tuberculosis has been reported (www.defra.gov.uk/animalh) and continues to occur in developing countries. The epidemiological impact of bovine tuberculosis on human health has not been assessed and is a major lacuna in developing countries. However with reports of tuberculosis due to M. bovis in AIDS patients (Bouvet et al., 1993; O'Reilly et al., 1995) and with increasing incidence of tuberculosis globally, rapid and reliable diagnostic assays are required not only for detection but also identification of the pathogenic mycobacteria in clinical samples. This is essential for prompt diagnosis, treatment land control of tuberculosis. Identification of human pathogenic mycobacteria becomes all the more relevant with the need to develop alternate new generation vaccines for human use. --

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Please delete the paragraph on page 20, lines 10-25 to page 21, lines 1-21 of the specification as originally filed and replace it with the following amended paragraph:

-- RFLP of PCR Amplicons of hupB gene derived from M. tuberculosis and M. bovis: DNA from different isolates of M. tuberculosis and M. bovis (listed in Table I) were amplified using N, Seq ID No. 1 and S, Seq ID No. 2 primers (645 bp fragment, Table II) and (ii) M, Seq ID No. 3 (internal primer) and S, Seq ID No. 2 (318 bp fragment, Fig: 4C, Table II, Fig: 1). PCR amplicons obtained from the DNA of M. bovis strains (lanes 4-11, Fig: 4B and 4C) were smaller in size as compared to the PCR amplicons obtained from the M. tuberculosis strains (lanes 1-3, Fig: 4B and 4C). The results of the PCR assay with the 2 sets of primers have been summarized in Table III. --